AMENDED IN SENATE APRIL 15, 2004 AMENDED IN SENATE MARCH 18, 2004

SENATE BILL

No. 1275

Introduced by Senator Ortiz

(Coauthor: Assembly Member Goldberg)

February 13, 2004

An act to add Sections 1264 and 1264.5, 1264.5, and 1264.6 to the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

SB 1275, as amended, Ortiz. Hospitals: maternity services: infant feeding assistance.

Under existing law, the State Department of Health Services regulates the licensure and operation of health facilities, including general acute care hospitals. Violation of these provisions is a crime.

This bill would recommend that a general acute care hospital provide or arrange for the provision of basic lactation management training, and safe preparation and appropriate bottle feeding techniques of infant formula for all health care practitioners who are permitted to provide these services in the hospital's maternity unit. The bill would allow a licensed nurse to demonstrate proficiency in basic lactation management, in accordance with standards established by the department, in lieu of completing the training and who regularly work the majority of their hours in the hospital maternity unit and nursery.

This bill would recommend that a general acute care hospital adopt a policy prohibiting prohibit the marketing of infant formula and the distribution of free formula samples in the hospital's maternity, nursery, or any other location, except under designated circumstances. The bill

SB 1275 **- 2 —**

would also prohibit the display of these products, or placards or posters concerning these products, or the distribution of materials provided by a manufacturer or distributor. It would authorize the donation or low-price sale of infant formula to a hospital, under certain conditions. The bill would prohibit a manufacturer of infant formula from marketing or distributing free samples in the hospital. The bill would require the department to consider a hospital's compliance with these provisions when conducting a licensing, audit, or certification review of a maternity ward of nursery. The bill would also prohibit a hospital from acting as an agent for distribution of infant formula.

This bill would establish a task force of interested parties to support a plan to transition labor and delivery hospitals in California to 'Baby Friendly' status, as defined by the World Health Organization. The bill would declare legislative intent that the task force operate as a subcommittee of the state Breastfeeding Promotion Advisory Committee. It would condition the activities of the task force upon the availability of public and private resources and funding.

This bill would provide that its provisions do not require the adoption of regulations pursuant to the Administrative Procedure Act.

By expanding the definition of a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 **SECTION 1.** The Legislature finds and declares:

- 2 (a) All new mothers should receive noncommercial, 3 evidence-based information from health care providers that 4 supports their ability to make an informed infant feeding choice,
- and the best choice for themselves and their families. Existing law 5 requires all general acute care hospitals, as defined in subdivision
- (a) of Section 1250 of, and all special hospitals providing
- maternity care, as defined in subdivision (f) of Section 1250 of, the

— 3 — SB 1275

Health and Safety Code, to make available a breastfeeding consultant or, alternatively, provide information to the mother on where to receive breastfeeding information. While the intent of the Legislature in enacting the current law was to allow women to receive the breastfeeding support they need in the early postpartum period, the reality is that in many cases, the law is not being implemented because there are no provisions for enforcement. Instead, women encounter multiple barriers during this vulnerable time, including lack of adequate assistance from health care providers and commercial messaging and free samples of formula, which can undermine their choice to breastfeed.

- (b) The national goals as set by Healthy People 2010 are for at least 75 percent of women to initiate breastfeeding, for at least 50 percent to still be breastfeeding at six months, and at least 25 percent by 12 months. Furthermore, the American Academy of Pediatries recommends that infants should be exclusively breastfed for approximately six months before being introduced to complementary foods. The American Academy of Pediatries further recommends that breastfeeding continue for at least 12 months, and thereafter for as long as mutually desired.
- (c) Too few women in California exclusively breastfeed their infants in the early postpartum period, let alone in the first six months of life, as recommended by the American Academy of Pediatrics. According to the most recent in-hospital breastfeeding data collected by the State Department of Health Services, 42 percent of California mothers are exclusively breastfeeding their babies at the time of hospital discharge. Another 40 percent of California mothers are breastfeeding combined with infant formula supplements at the time of hospital discharge, already compromising breastfeeding efforts and leading to early cessation of breastfeeding. According to the American Academy of Family Physicians, the strongest evidence indicates that the positive effects of breastfeeding are most significant with six months of exclusive breastfeeding. Additionally, studies show that the effects are closely related with improved outcomes being associated with longer breastfeeding duration.
- (d) There are also racial and ethnic disparities with regard to breastfeeding rates. While 64 percent of white women in California are exclusively breastfeeding in the hospital, only 39

SB 1275 — 4 —

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percent of Asian/Pacific Islanders, 30 percent of African-American women, and 30 percent of Latinas are doing so.

- (e) Billions of health care dollars would be saved if more infants were exclusively breastfed and breastfed for a longer duration of time. The United States Department of Agriculture (USDA) estimates that \$2 billion per year are spent by families on infant formula and that between \$3.6 and \$7 billion health care dollars could be saved each year in preventable conditions if breastfeeding rates were increased to the recommended levels.
- (f) There is consensus among health care experts and institutions that breastfeeding is the superior method of feeding and nurturing infants due to evidence from a plethora of scientific research. The American Dietetic Association states that "[h]uman milk provides optimal nutrition to the infant, with its dynamic composition and the appropriate balance of nutrients provided in easily digestible and bioavailable form." According to the American Academy of Pediatrics 1997 Policy Statement, "[h]uman milk is uniquely superior for infant feeding and is species-specific; all substitute feeding options differ markedly from it. The breastfed infant is the reference or normative model against which all alternative feeding methods must be measured with regard to growth, health, development, and all other shortand long-term outcomes." The policy statement also asserts that "[r]esearch in the United States, Canada, Europe, and other developed countries, among predominately middle-class populations, provides strong evidence that human milk feeding decreases the incidence and/or severity of diarrhea, lower respiratory infection, otitis media, bacteremia, bacterial meningitis, botulism, urinary tract infection, and necrotizing enterocolitis." There are a number of studies that show a possible protective effect of human milk feeding against sudden infant death syndrome, insulin-dependent diabetes mellitus, Crohn's disease, ulcerative colitis, lymphoma, allergic diseases, and other ehronic digestive diseases. The American College of Obstetricians and Gynecologists' 2000 educational bulletin, "Breastfeeding: Maternal and Infant Aspects" addresses how breastfeeding can impact maternal health, stating that "[b]reastfeeding lessens the mother's postpartum blood loss, allows bonding with the infant, decreases the risk of ovarian cancer and premenopausal breast cancer, reduces the incidence of pregnancy induced, long-term

5 SB 1275

obesity, and can serve, if used under well-defined guidelines, as natural birth control by delaying ovulation."

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- (g) There are few absolute contraindications to breastfeeding. According to the American Academy of Pediatrics, these include the infant with galactosemia and infants of mothers who use illegal drugs, have untreated active tuberculosis, and have been infected with the human immunodeficiency virus. Most prescription and over-the-counter medications are safe for the breastfed infant with the exception of radioactive isotopes, antimetabolites, cancer ehemotherapy agents and a small number of other medications.
- (h) "Breastfeeding: Investing in California's Future," the Breastfeeding Promotion Committee Report to the California Department of Health Services Primary Care and Family Health (1996) found that "women look to health care providers for breastfeeding information and support; however, health care systems, policies, and personnel often unknowingly interfere with the initiation and continuation of breastfeeding. In addition, many women do not have access to appropriate breastfeeding resources." This report also states that health care professionals are in a key position to affect breastfeeding success and promotional efforts will be successful only if women who are encouraged to breastfeed encounter providers who are able to respond to their needs. In addition, the differences in hospital policies regarding new mother counseling on infant feeding are varied and followup training provided to hospital staff also differ from employer to employer. Due to these issues and differences, a recommended state standard for training on infant feeding techniques will promote awareness among health care professionals of model guidelines and move toward improvement in the delivery of these services.
- (i) While breastfeeding is the best infant feeding choice for most mothers and babies, all families deserve to receive appropriate counseling on infant feeding, whether they choose to breastfeed or formula feed. Mothers who choose or need to use formula should receive education on the safe preparation of formula and appropriate bottle-feeding techniques. Low-income women, those with low educational attainment and non-English-speaking mothers are particularly vulnerable to a lack of knowledge about how to formula feed safely, placing their infants at greater risk. Formula that is underdiluted or overdiluted

SB 1275 -6-

can result in serious health problems for infants. Propping a bottle carries risks, such as increased ear infections, aspiration, increased dental caries, and inadequate parent-child attachment. Bottle feeding also carries a greater risk of overfeeding, which may be a contributing factor in childhood obesity.

- (j) Learning to breastfeed can take time and practice, making what occurs in the early postpartum period critical to the establishment of lactation. Though a normal breastfed newborn will usually readily take a bottle when it is put into its mouth, it is commonly difficult to get a newborn to accept the breast once bottle feeding has been initiated. The use of infant formula supplements has the negative effect of interfering with the baby's ability to attach to the breast correctly and decreasing a woman's milk supply, leading the woman to use more formula and undermining her confidence in her ability to breastfeed.
- (k) Research demonstrates that exposure to infant formula literature and free infant formula samples decreases exclusive breastfeeding and is associated with infant formula supplementation, which can lead to early weaning. According to the Cochrane Database of Systematic Review, a professional resource for hospital, research, and teaching institutions, "giving of commercial hospital discharge packs to mothers of newborn babies lowers the extent of exclusive breastfeeding." This conclusion was based on nine randomized controlled trials involving a total of 3,730 women. In addition, according to survey results from the State Department of Health Services 2001 Survey of California Hospitals-Infant Feeding Policies and Practices, distribution of discharge packs containing infant formula or infant formula coupons was negatively associated with higher rates of exclusive breastfeeding practices and hospitals that use educational material from formula companies were more likely to have lower exclusive breastfeeding rates.
- (l) New mothers deserve the right to make informed decisions about infant feeding based on information that is free of commercial influence. Instead of placing the health of women and babies at risk by facilitating formula marketing, health care institutions should provide women with the factual and scientific information needed to truly make an informed choice about infant feeding.
 - SECTION 1. The Legislature finds and declares as follows:

—7— SB 1275

(a) All new mothers deserve to receive evidence-based information from health care providers that supports their ability to make an informed infant feeding choice, and the best choice for themselves and their families. New mothers deserve the right to make these important decisions free of commercial influence. The intent of this act is not to prohibit the giving of gifts, including diaper and baby care bags, to new mothers in hospitals, but instead to eliminate the infant formula marketing tools that often are inappropriately packaged as gifts. Additionally, it is the intent of this act to be independent of any arrangement made by a hospital for obtaining formula for mothers who choose or need it. Instead of placing the health of women and babies at risk by facilitating formula marketing, the role of health care institutions should be to provide women with the factual and scientific information needed to make an informed choice about infant feeding.

- (b) Existing law requires all general acute care hospitals, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, and all special hospitals providing maternity care, as defined in subdivision (f) of Section 1250 of the Health and Safety Code, to make available a breastfeeding consultant or, alternatively, provide information to the mother on where to receive breastfeeding information. The intent of this law was to allow women to receive the breastfeeding support they need in the early postpartum period. However, the policy and its implementation can be strengthened. Women encounter multiple barriers during this vulnerable time, including lack of adequate assistance from providers and commercial messaging and free samples of formula, which, combined, can undermine their choice to exclusively breastfeed.
- (c) The national goals, as set by Healthy People 2010, are for at least 75 percent of women to initiate breastfeeding, for at least 50 percent to still be breastfeeding at six months, and at least 25 percent by 12 months. Furthermore, the American Academy of Pediatrics recommends that infants should be exclusively breastfed for approximately six months before being introduced to complementary foods. According to the American Academy of Family Physicians, the strongest evidence indicates that the positive effects of breastfeeding are most significant with six months of exclusive breastfeeding. The American Academy of

SB 1275 — 8 —

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39 40 Pediatrics further recommends that breastfeeding continue for at least 12 months, and thereafter for as long as mutually desired.

- (d) According to the most recent in-hospital breastfeeding data collected by the State Department of Health Services, 42 percent of California mothers are exclusively breastfeeding their babies at the time of hospital discharge. Another 40 percent of California mothers are breastfeeding combined with infant formula supplements at the time of hospital discharge, already compromising breastfeeding efforts and leading to early cessation of breastfeeding. There are racial and ethnic disparities with regard to breastfeeding rates. While 64 percent of white women in California are exclusively breastfeeding in the hospital, only 39 percent of Asian/Pacific Islanders, 30 percent of African-American women, and 30 percent of Latinas are doing so.
- (e) The United States Department of Agriculture (USDA) estimates that \$2 billion per year are spent by families on infant formula and that between \$3.6 and \$7 billion health care dollars could be saved each year in preventable conditions if breastfeeding rates were increased to the recommended levels.
- (f) According to the American Academy of Pediatrics 1997 Policy Statement, "(h)uman milk is uniquely superior for infant feeding and is species-specific; all substitute feeding options differ markedly from it. The breastfed infant is the reference or normative model against which all alternative feeding methods must be measured with regard to growth, health, development, and all other short- and long-term outcomes." The policy statement also asserts that "(r)esearch in the United States, Canada, Europe, and other developed countries, among predominately middle-class populations, provides strong evidence that human milk feeding decreases the incidence and/or severity of diarrhea, lower respiratory infection, otitis media, bacteremia, bacterial meningitis, botulism, urinary tract infection, and necrotizing enterocolitis." There are a number of studies that show a possible protective effect of human milk feeding against sudden infant death syndrome, insulin-dependent diabetes mellitus, Crohn's disease, ulcerative colitis, lymphoma, allergic diseases, and other chronic digestive diseases. The American College of Obstetricians and Gynecologists' 2000 educational bulletin, "Breastfeeding: Maternal and Infant Aspects" addresses how breastfeeding can impact maternal health, stating that "(b)reastfeeding lessens the

—9— SB 1275

mother's postpartum blood loss, allows bonding with the infant, decreases the risk of ovarian cancer and premenopausal breast cancer, and reduces the incidence of pregnancy induced and long term obesity."

- (g) There are few absolute contraindications to breastfeeding, including maternal HIV positive status, substance abuse, chemotherapy, and active tuberculosis. Infants with galactosemia should not be breastfed. Most prescription and over-the-counter medications are safe for the breastfed infant with the exception of radioactive isotopes, antimetabolites, cancer chemotherapy agents and a small number of other medications.
- (h) "Breastfeeding: Investing in California's Future," the Breastfeeding Promotion Committee Report to the California Department of Health Services Primary Care and Family Health (1996) found that "health care systems, policies, and personnel often unknowingly interfere with the initiation and continuation of breastfeeding. In addition, many women do not have access to appropriate breastfeeding resources." This report also states that health care professionals are in a key position to affect breastfeeding success and promotional efforts will be successful only if women who are encouraged to breastfeed encounter providers who are able to respond to their needs.
- (i) While breastfeeding is the best infant feeding choice, mothers who choose or need to use formula should receive education on the safe preparation of formula and appropriate bottle-feeding techniques. Low-income women, those with low educational attainment and non-English-speaking mothers are particularly vulnerable to a lack of knowledge about how to formula feed safely, placing their infants at greater risk. Formula that is underdiluted or overdiluted can result in serious health problems for infants. Propping a bottle carries risks, such as increased ear infections, aspiration, increased dental caries, overfeeding, and inadequate parent-child attachment.
- (j) Learning to breastfeed can take time and practice, making what occurs in the early postpartum period critical to the establishment of lactation. Though a normal breastfed newborn will usually readily take a bottle when it is put into its mouth, it is commonly difficult to get a newborn to accept the breast once bottle feeding has been initiated. The use of infant formula supplements has the negative effect of interfering with the baby's

SB 1275 **— 10 —**

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39 40 ability to attach to the breast correctly and undermining the mother's confidence in her ability to breastfeed.

- (k) Research demonstrates that exposure to infant formula literature and free infant formula samples decreases exclusive breastfeeding and is associated with infant formula supplementation, which can lead to early weaning. According to survey results from the State Department of Health Services 2001 Survey of California Hospitals-Infant Feeding Policies and Practices, distribution of discharge packs containing infant 10 formula or infant formula coupons was negatively associated with higher rates of exclusive breastfeeding practices and hospitals that use educational material from formula companies were more likely to have lower exclusive breastfeeding rates.
 - SEC. 2. Section 1264 is added to the Health and Safety Code, to read:
 - 1264. (a) A general acute care hospital is recommended to provide or arrange for the provision of basic lactation management training for all health care practitioners who are permitted to provide these services in the hospital's maternity unit and who regularly work the majority of their hours in the hospital maternity unit and nursery. Training curricula selected by hospitals shall should be based on breastfeeding management guidelines that are evidence-based, consistent, accurate, and clinically appropriate in order to effectively impact breastfeeding initiation and duration, and that are based on the following International Lactation Consultant Association's "Evidence-Based Guidelines for Breastfeeding Management during the First Fourteen Days":
 - (1) Human milk provides all of the fluid and nutrients necessary for optimal infant health, growth, and development.
 - initiation of breastfeeding (2) Early facilitates establishment of lactation.
 - (3) Exclusive breastfeeding should be encouraged and facilitated for healthy mothers with healthy, term infants.
 - (4) Use of supplements or pacifiers in the hospital is associated with a risk for early weaning and should be avoided unless medically indicated.
 - (5) Attention to early feeding cues facilitates correct latch-on and effective suckling.
 - (6) Unrestricted breastfeeding (8-12 times per 24 hours) promotes adequate milk production and enhances infant health.

— 11 — SB 1275

(7) Milk transfer occurs more readily with appropriate positioning and latch-on.

(8) Rooming-in facilitates the breastfeeding process.

- (9) Assessment is a prerequisite to intervention and should include recognition of signs of effective and ineffective breastfeeding.
- (10) Identification of maternal risk factors for breastfeeding difficulties allows for appropriate assistance and followup.
 - (11) There are few absolute contraindications to breastfeeding.
- (12) Providing anticipatory guidance that includes realistic expectations of the breastfeeding process can prevent premature weaning.
- (13) Ensuring that materials and services are appropriately provided considering the woman's cultural background, education, and primary language.
- (b) A general acute care hospital is recommended to provide or arrange for the provision of training on the safe preparation and appropriate bottle-feeding techniques of infant formula for all health care practitioners who are permitted to provide these services in the hospital's maternity unit and who regularly work the majority of their hours in the hospital maternity unit and nursery. Training curricula selected by hospitals should include the following principles based on education and training materials developed by the Women, Infants, and Children Program Branch of the State Department of Health Services:
- (1) Formula feeding carries risks and improper use can lead to hazards.
- (2) Breastfeeding is the normal standard on which to base infant feeding patterns.
- (3) Babies should always be held when bottle-feeding to maximize bonding and to prevent the risks associated with bottle propping.
- (4) Reading and following directions for the preparation of all types of formula is vitally important to prevent the misuse of formula and negative impacts on the infant.
- (5) Proper sanitation of bottles and artificial nipples prevents rapid bacterial growth.
- (6) Providing anticipatory guidance on when to discard unused infant formula in the bottle and in the refrigerator prevents rapid bacterial growth.

SB 1275 — 12 —

(7) The use of infant formula results in an increased cost in caring for the infant and may vary according to the type of formula and brand of formula being consumed.

- (8) Providing anticipatory guidance regarding formula intolerance may prevent frequent formula switching.
- (9) Ensuring that materials and services are appropriately provided considering the woman's cultural background, education, and primary language.
- (c) This section does not require the adoption of regulations pursuant to the rulemaking provisions of the Administrative Procedure Act (Chapter 3 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).
- SEC. 3. Section 1264.5 is added to the Health and Safety Code, to read:
- 1264.5. (a) No manufacturer of infant formula may market infant formula and distribute free infant formula samples in the hospital's maternity unit, nursery, or any other location in the hospital nor may the hospital act as an agent for distribution. This section shall not limit the ability of a hospital to provide noncommercial information about formula and formula feeding, or to provide infant formula pursuant to paragraphs (1) and (2). The provision of formula under these circumstances shall include instruction on the safe and proper use of formula in a culturally and linguistically competent manner.
- (1) This section shall not prevent a new mother from receiving formula from the hospital needed to feed her baby while in the hospital under both or either of the following circumstances:
- (A) The mother chooses to formula feed and therefore requests formula
- (B) The mother is directed by a physician, or a physician determines, that there is a medical need for formula feeding or formula supplementation or due to a preexisting medical contraindication that prevents her from breastfeeding. The provision of formula under this circumstance shall include instructions on the safe and proper use of formula.
- (2) This section shall not prevent the hospital from providing feeding supplies to be taken home for children with special needs who require formula supplementation or exclusive formula feeding due a medical condition, as directed by the attending physician.

—13 — SB 1275

(b) A hospital's maternity unit and nursery may not be used for display of products, or placards or posters concerning these products, or for the distribution of material provided by a manufacturer or distributor.

- (c) Donations or low-price sales to a hospital of supplies of infant formula for use as outlined in subdivision (a) may be made. The formula may bear a company's name or label.
- (c) The provisions of this section are independent of any arrangement made by an individual hospital for obtaining formula.
- (d) The following definitions apply for purposes of this section:
- (1) "Infant formula" means a breast milk substitute formulated industrially, *according to standards of the federal Food and Drug Administration*, to satisfy the normal nutritional requirements of infants.
- (2) "Label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a container of any products within the scope of this section.
- (3) "Manufacturer" means a corporation or other entity in the public or private sector engaged in the business or function, whether directly or through an agent or through an entity controlled by or under contract with it, of manufacturing infant formula.
- (4) "Marketing" means product promotion, distribution, selling, advertising, product public relations, and information services.
- (4) "Market" means product promotion, distribution, sales, advertising, product public relations, and information services. This definition is limited to infant formula products produced by a manufacturer, as defined in paragraph (3). For purposes of this definition, "distribution" shall not include the provision of formula permitted under the circumstances described in subparagraphs (A) and (B) of paragraph (1) of subdivision (a).
- (5) "Samples" means single or small quantities of a product provided without cost.
- 38 (6) "Supplies" means quantities of a product provided for use over an extended period, free or at a low price.

SB 1275 — 14 —

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(e) The department shall consider compliance with this section and Section 1264 when it conducts any licensing, audit, or certification review of hospital maternity wards and nurseries. SEC. 4.

(e) This section does not require the adoption of regulations pursuant to the rulemaking provisions of the Administrative Procedure Act (Chapter 3 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

SEC. 4. Section 1264.6 is added to the Health and Safety Code, to read:

1264.6. (a) There is hereby established a task force of interested parties to develop and support a plan to transition labor and delivery hospitals in California to "Baby Friendly" status, pursuant the World Health Organization definition. It is the intent of the Legislature that this task force function as a subcommittee of the existing Breastfeeding Promotion Advisory Committee, convened by the Primary Care and Family Health Division of the State department. The leadership and members of this current committee, under the advice and counsel of the department, shall establish the membership, activities, and timelines for this task force. The activities of the task force shall be conditioned upon the availability of public and private resources and funding, including federal Women, Infants, and Children Supplemental Nutrition Program funds, when appropriate, approved, and available, and in-kind contributions and support from philanthropic and other private organizations, including the American Academy of Pediatrics, California District. The activities of this task force shall function only to the extent that resources allow.

- (b) This section does not require adoption of regulations pursuant to the rulemaking provisions of the Administrative Procedure Act (Chapter 3 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).
- 33 SEC. 5. No reimbursement is required by this act pursuant to 34 Section 6 of Article XIII B of the California Constitution because 35 the only costs that may be incurred by a local agency or school 36 district will be incurred because this act creates a new crime or 37 infraction, eliminates a crime or infraction, or changes the penalty 38 for a crime or infraction, within the meaning of Section 17556 of 39 the Government Code, or changes the definition of a crime within

— 15 — SB 1275

- 1 the meaning of Section 6 of Article XIII B of the California 2 Constitution.